Opioid Reduction Program for Total Knee Replacement Patients Manual of Procedures

NCT05414942

Version Date: October 5, 2021

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FUNDING

Tennessee Clinical and Translational Science Institute, *Opioid Reduction for Total Knee Replacement Patients.* 2021-2020. Total costs: $30,000.

PROJECT OVERVIEW

Purpose

The purpose of this work is to examine the efficacy of a brief intervention to reduce opioid use following total knee replacement.

We will conduct a randomized clinical trial to test our newly adapted Opioid Reduction Program ORP (vs. Treatment As Usual; TAU) for a population of patients presenting for Total Knee Replacement (TKR) surgery (N=100). Our intervention will include a discussion of the risks of opioid use, pain management through nonnarcotic medication and mindfulness techniques, and opioid weaning strategies[1] that will assist patients with reductions in opioid use, even for those with chronic pain. We will assess outcomes using opioid refill requests, prescription drug monitoring, and pill counts of opioid medication at 4 weeks (short term follow up) and 12 weeks (long term follow up) following TKR surgery.

Aim 1: Examine the efficacy of our ORP vs. TAU control in reducing opioid use among TKR surgery patients. Opioid use following TKR surgery will be assessed via daily diaries, pill counts, medical chart review of prescription refills, and prescription drug monitoring for opioid refills from other physicians.

Hypothesis 1: We hypothesize that at 4 weeks, a higher percentage of those in the OPR group will express an intent to reduce future opioid medication use as compared with those in TAU.

Hypothesis 2: We hypothesize that those in the ORP will have lower cumulative exposure to opioid medication (i.e., morphine milligram equivalents [MMEs] at 12 weeks) than those in TAU.

Aim 2: Examine the relation between opioid use and TKR functional recovery following surgery.

Hypothesis 3: We predict that those who reduce their opioid use (as evidenced by fewer MMEs) will engage more in activities that will increase range of motion and functional knee use (e.g.,physical therapy and at-home exercises), thereby increasing the speed of recovery.

Background

According to the 2017 National Survey on Drug Use and Health data, 11.4 million Americans over age 12 reported the misuse of opioid medication in the past year, demonstrating that opiate misuse is a critical public health problem.[2,3] Opioid misuse and use disorder are likely to develop from prescribed use.[4] Evidence suggests that greater exposure (in terms of medication strength and length of use) is linearly related to risk of later misuse.[5,6] Recent medical claims research indicates that among opioid naïve patients (N=536,767), those who fill opioid prescriptions 1 time are 2.9% more likely to become long term users (vs. non-opioid users), whereas those who fill 4 or more times are 26.1% more likely to use opioids long term.[5,6] Further, continued exposure to opioids can produce hyperalgesia in some patients, lowering their pain threshold and leading them to crave more opioid analgesic.[7-10]

When considering the risk of exposure, orthopedic surgery settings are a clear point of intervention. Orthopedic surgeries are associated with the prescribing of more opioids than any other surgical specialty,[11] particularly for total knee replacement surgery (TKR),[12] which is associated with severe post-operative pain.[13] Research suggests that this pain tends to last for extended periods in some patients; Significant pain (visual analog scale score of > 40) is reported by 44.4% of patients at 1 month post-surgery, 22.6% of patients at 3 months post-surgery, 18.4% of patients at 6 months post-surgery, and 13.1% of patients at 12 months post- surgery.[14] Management of this pain can lead to lengthy opioid exposure; Namba et al. found that of 24,105 TKR patients, 9,914 (41.5%) continued opioid use after 12 weeks.[15] Further, the population of individuals presenting for TKR surgery is increasing at an exponential rate,[16] and research indicates a need for increased communication between surgeons and patients regarding appropriate opioid analgesic use before and after surgery.[17,18] Research from other specialties suggests that surgery specific counseling can reduce functional recovery time and reliance on opioid analgesic,[19] although no studies have explored these outcomes in TKR patients.

Rationale

In the context of prescribed opioids, research suggests that increased exposure is associated with long-term opioid use. Orthopedic surgeries are associated with the prescribing of more opioid narcotics than any other surgical specialty, particularly for Total Knee Replacement surgery, which is associated with severe post-operative pain. The proposed project is a randomized clinical trial to explore the efficacy of our Total Knee Replacement Opioid Reduction Program (ORP) vs. Treatment As Usual (TAU) in the reduction of opioid use following total knee replacement surgery.

Intervention Content:

1. Psychoeducation
2. Non narcotic pain management
3. Mindfulness

Population

We will recruit a large sample of patients (N=100) who present for TKR surgery at Campbell Clinic. Participants must be 18 years of age or older.

Eligibility

Inclusion Criteria

To be eligible to participate, participants must meet the following requirements:

- Presenting for a pre-operatory appointment at Campbell Clinic for TKR surgery that will result in the prescribing of opioid medication
- 18 years of age or older
- Have access to a telephone
- Be able to understand consent procedures

Exclusion Criteria

Those that exhibit any of the following will be ineligible to participate:

- Contraindication to opioid medications

Research Design

This is a randomized, controlled clinical trial in which participants will be randomized 1:1 to one of two arms: TKR ORP intervention or treatment-as-usual (TAU).

Randomization will occur on a 1:1 ratio in blocks of 4.

Outcome Measures

Outcomes Aim 1: We will assess regular opioid use prior to and following surgery, using a daily diary of opioid medication use, opioid medication pill counts, information transcribed from the medical file (medication prescribed and prescription refill requests), and prescription drug monitoring data.

Outcomes Aim 2: We will assess functional recovery using the Knee Injury and Osteoarthritis Outcome Score.[24] In addition to our main outcomes, we will assess potential confounders and moderators of treatment, including history of and current chronic pain,[25] pain catastrophizing,[26] opioid tolerance and craving,[27,28] adverse events, knowledge about opioid risks prior to/following intervention, and transcribed surgical specifics from the medical file (analgesia, complications).

PROCEDURES

Recruitment

Recruitment of participants will be done exclusively through Campbell Clinic. Potential participants will be identified by Drs. William "Bill" Mihalko, Marc Mihalko, Ford, Guyton, Crockarell, and Harkess (or their assistants) or study staff from the surgery schedule, which requires access to Campbell Clinic's electronic health record (ehr SRS). Remaining inclusion and exclusion criteria will be determined from a screening measure conducted prior to enrollment and randomization.

Recruitment Script

Introduction: Hi, My name is [Name] from the University of Tennessee Health Science Center. We are partnered with the Campbell Clinic to recruit patients into the TKR Study, a project where we talk to people about their medication following total knee replacement surgery. Your surgeon, [Surgeon's Name], is one of our partners, so I wanted to introduce myself to you and see if you'd be interested in learning more about a study for Total Knee Replacement patients.

If they <u>don't</u> seem interested: No worries, thank you for your time. If you change your mind, feel free to reach out to your doctor or [Doctor's Assistant's Name] anytime before your surgery. They can give you my information.

If they seem interested: Great! The TKR Study's goal is to test a behavioral treatment program in Total Knee Replacement surgery patients. The purpose is to educate patients on appropriate use of opiate pain medications. If you wanted to participate, you would need to complete 3 or 4 visits with us, depending on which group you are placed in. If you are in the control group (treatment as usual), you will just have 3 visits. The first visit is before your surgery and will take approximately 30 minutes. The last 2 visits will be 4 weeks and 12 weeks after your surgery, and they should take about 15 minutes to complete. The other group you could be placed in is the intervention group, which is the group that receives the counseling sessions for appropriate opioid use. If you are in that group, you will have an extra visit 2 weeks after your surgery. It shouldn't last longer than 20 minutes. These visits can be done after your scheduled visits at Campbell Clinic or they can be done over the phone, whichever is more convenient to you. There is no cost to you. We will compensate you for your time with electronic Amazon gift cards. If you complete the 1st visit, 4 week visit, and 12 week visit, you will receive a total of $150 for your time.

Does this sound like something you'd like to do? *(If **yes**: screen for eligibility and begin baseline visit procedures or schedule a baseline visit).*

Cascade of Events

<u>Baseline</u>

- Contact potential participants prior to surgery to provide information about participation

- Screening for eligibility/exclusionary criteria
- Informed Consent
- Baseline assessments
    - Contact Information
    - Demographics
    - History of opioid use
    - Non-narcotic pain medication use
    - Knowledge pre-test
    - Quality and intensity of pain (SF-MPQ-2)
    - Short and long-term patient-relevant outcomes (KOOS JR)
    - Pain catastrophizing
- Randomization to Opioid Reduction Program (ORP) vs. Treatment As Usual (TAU; no intervention)
- ORP only:
    - For the experimental group:
        - ORP discussion including the following topics: risks of opioid use, tolerance and addiction, consequences of using opioids with alcohol or other sedatives, appropriate use of opioid medication, use of acetaminophen/ibuprofen in place of opioid, and appropriate disposal of opioid
- Provide incentive (Amazon gift card sent directly to participant's email, or ordered and printed for participant to take) for participation in visit 1
- Set appointment date/time for booster (ORP arm) or 4-week follow-up (TAU arm)

ORP only: Booster Session (In-person at Campbell Clinic or over-the-phone, 2wks post op)

- Delivery of ORP booster intervention 2-weeks after surgery

4-Week Follow-Up (In-person at Campbell Clinic or over-the-phone)

- Assessment of: Opioid medication pill count and regimen (when taken, number of pills taken per dose), pain in the days following surgery, current pain, knowledge post-test, use of other pain management, and self-report of opioid takeback for disposal, opioid tolerance and craving, adverse events, opioid daily diary.
- Medical record abstraction including surgery specifics (analgesia, complications), functional recovery, and medication refills.
- Provide incentive for participation in follow-up (Amazon gift card sent directly to participant's email, or ordered and printed to mail to participant)

12-Week Follow-Up (In-person at Campbell Clinic or over-the-phone)

- Assessment of: Opioid medication pill count and regimen (when taken, number of pills taken per dose), pain in the days following surgery, current pain, knowledge post-test, use of other pain management, and self-report of opioid takeback for disposal, opioid tolerance and craving, adverse events, opioid daily diary.
- Medical record abstraction including medication refills and functional recovery.
- Provide incentive for participation in follow-up (Amazon gift card sent directly to participant's email, or ordered and printed to mail to participant)

Baseline Visit

Prior to surgery, interested patients will be assessed for inclusion/exclusion criteria. Those who are eligible will be consented prior to participation. After consent, we will collect baseline measures, and participants will be randomized. Those randomized to the intervention arm will receive the intervention during this visit.

Please see the measures section to review which measures are used during the Baseline visit.

Screening

Eligibility will be determined by both chart review and self-report. Potential participants will be informed about the general overview of the study. If the patient expresses interest in the study, the Eligibility Questionnaire will then be administered to determine eligibility. (This can also be done at the beginning of a scheduled Baseline Visit before consent).

Informed Consent

The consent of the subject will be obtained at the first study visit at the participant's physician visit. If in-person is not possible, informed consent can also be done over-the-phone using either Docusign (digital signature) or by mailing the potential participant the current consent form. Please note if mailing: the participant's surgery date should be more than 2 weeks out to give adequate time for it to reach the participant and return to us.

Inviting the subject to read and sign the consent form is not sufficient for securing informed consent. Study staff will explain the nature of the study and answer all questions regarding the study. A copy of the informed consent will be given to the subject, and the original(s) will be placed in the subjects' research record. An entry documenting informed consent must also be made in the subjects' research record to confirm that informed consent was obtained prior to any study-related procedures and that the subject received a signed copy. The objection of any subject in word or action to the performance of study procedures will be sufficient for their withdrawal or exclusion from the study.

Illiterate English Speaking Subjects Procedures (from the IRB):

1. Potential subjects who are mentally competent and understand English, but who do not read or write English (i.e., are illiterate), may be enrolled in research studies by making or placing an "X" on the consent document in the space for the participant signature after the study information has been reviewed with them.
2. Upon verbal explanation, the potential subject should be able to: a. describe the study procedures in lay terms and appreciate what will be involved in participation in the study, b. understand the risk(s) and benefit(s) of being in the study, and c. indicate approval or disapproval regarding participation in the study.

3. The person obtaining the consent should ascertain the above and document in the research record the method(s) utilized to communicate with the subject and the method(s) utilized by the subject to communicate agreement to enter the study.
4. A signed copy of the informed consent document shall be given to the subject or his or her legally authorized representative.
5. Video and audiotaping of the process may be utilized with permission of the individual and in accordance with the institution's policies.

Study procedures will not continue until a signed consent form is received. Please note: if the consent is done by mail, we cannot do any study procedures or collect information until we receive the signed consent form back in the mail.

If a participant decides NOT to consent, the process will immediately be stopped, and the consent form will be voided. The participant will be given an ID number in the database, classified as "Did Not Consent", and no information will be stored except for their MRN number.

Profile Information & Assessments

After informed consent is complete, the next step is to collect profile information within the database. This includes information such as:

- Participant's first/last name
- Phone number
- Mailing address
- Email
- Best method of contact
- Alternate Contact
- Surgery date
- Etc.

After filling out all the necessary profile information, select "create visit checklist" in the database, and it should take you to the questionnaires for Visit 1 (Baseline). The assessments should now be administered, starting with demographics and ending with the knowledge pre-test. Once each measure is complete, you will notice the box in the database turns a different color to reflect that. **With that being said, do not click on questionnaires in future visits, as this will mess up the database, and there is no way to reverse it.**

Randomization

Randomization happens during the Baseline Visit, after all the assessments are complete. *Please note that randomization and treatment (ORP) must occur during the same visit*. The randomization scheme is as follows:

CTSI-TKR is a prospective randomized clinical trial with two treatment arms (n = 50 each for a total of 100 participants): Opioid Reduction Program (ORP) and Treatment As Usual (TAU). Participants are individually

assigned to a study arm by stratified variable-block randomization (randomly chosen block-lengths of 4 or 6 and separate sequences in each of the two strata defined by sex/gender).

The randomization scheme was determined by the statistician and can be found under the "Study Management" folder. *Within the randomization log, simply locate the appropriate tab (according to your participant's gender) and find the next blank, which will tell you if that person is in ORP group (intervention) or TAU group (control). Make sure to fill out the study ID number, date of BV, and transfer the allocID to the participant's database profile.*

Intervention

Intervention will be delivered only to the ORP group, at the baseline visit and at a 2 week booster session, to prepare the patient for weaning off of opioids.

During the intervention the interventionist will provide information regarding:

- Harms associated with opioid use (e.g., overdose and accidents)
- Tolerance & addiction risk factors
- Pain expectation following TKR surgery
- Non-narcotic pain management techniques
- Proper disposal of unused medication

Please refer to the intervention manual for more details on the intervention, such as:

(a) Theoretical basis and overarching goals of the intervention
(b) Treatment Schedule
(c) Intervention Scripts
(d) Patient Handouts
(e) Interventionist Training
(f) Intervention Fidelity

The intervention manual is located on onedrive in the CTSI TKR Opioid folder. The manual is specifically within the intervention folder.

Follow-Ups & Data Abstraction

Following the baseline visit and surgery, we will engage with patients when they return to the Campbell Clinic for their Physical Therapy (PT) visits or over the phone to complete follow-up assessments. All participants will complete follow-up assessments with a Research Assistant (RA) blinded to treatment condition. Follow up assessments will occur at 4 weeks and 12 weeks following surgery.

Follow-ups consist of doing the measures for that visit and a data abstraction after the visit is complete.

Please see the measures section to review which measures are used during the follow-up visits.

4-week abstraction: This is a surgical note abstraction, meaning that we are looking for notes from the patient's physician within the Campbell Clinic health record system (SRS).

12-week abstraction: This will be a prescription based abstraction. Using the Campbell Clinic system and TN-CSMD will be required.

Campbell Clinic SRS

The Campbell Clinic SRS is available to staff members who have been credentialed at Campbell Clinic. This process is overseen by the study coordinator and Margaret Knack (Campbell Clinic Research Nurse Coordinator). In order to access the SRS system, staff must VPN into the Campbell Clinic server using this link: https://citrixnew.campbellclinic.com/vpn/index.html (username/password are the Campbell Clinic credentials). Once logged in, staff needs to select the orange "SRS" icon the right end of the screen. This will start a download process. Double click the download, and it will load the health record system. You will need to sign in again with Campbell Clinic credentials.

If for some reason it doesn't work, you will need to make sure you have Citrix Receiver downloaded and/or call Campbell Clinic's IT line: *901-435-5678.*

TN-CSMD

The TN-CSMD (Tennessee Controlled Substance Monitoring Database) is a database to monitor the dispensing of Schedule II, III, IV, & V controlled substances. We use this database during the 30-day data abstraction to see if the participant has been prescribed any opioids other than those prescribed by their Campbell Clinic surgeon.

Registration:

Accessing the TN-CSMD first requires a physician sponsor. We have used Dr. William Mihalko of Campbell Clinic in the past.

2. How do I register to access the CSMD database?

Go to www.tncsmd.com and click on the word "register" to begin the registration process. Completion of the registration process will require specific identifying elements. Once registration is complete and approved, you will receive an email with your username and instructions to create a password. Medical Examiner role is only for **State Medical Examiners.**

6. What happens if I do not have a Tennessee driver's license?

You can still register at www.tncsmd.com, but you will need to obtain a Tennessee State ID. You will input the Tennessee State ID number into the Driver License field when registering. If you hold a Driver's License from another state you can register with the CSMD, but it may require manual validation by the CSMD Team.

Using the CSMD:

18. How do I run a report to view the controlled substance history of a patient?

Once you are logged into the CSMD there is a step-by-step instruction available within the application by clicking the question mark () in the dark blue bar on the right side. This will display text instructions to walk you through a patient request. Hover over the REQUEST tab on the top navigation bar. Then choose "New Request" and a page will appear that defaults to a PATIENT report. Fill in the patient's LAST NAME, FIRST NAME, and DOB (date of birth). Scroll down the page and locate the Date Range. It defaults to the past year, but you can change that by clicking on the checkmark in the box and entering the dates correctly (mm/dd/yyyy). You must choose the type of report output you want, either "PDF" or "XLS". If you would like to query other states to determine if your patient has data, mark the appropriate checkbox by the states, and then click SUBMIT at the very bottom of the page.

The system will show you an indicator (a green spinning wheel or taskbar depending on your browser) while it is searching the database. Multiple state data will be return if the user is authorized to view another state's data. Once the taskbar disappears, a screen will come up with the "Patient Rx History Report" link in the middle of the page. Click on that link and the file can be Opened or Saved. This link is only used if running data on the CSMD. If you run a multi-state report, please click the "**Display all Results**" button **instead** of the "Patient Rx History Report" hyperlink.

COVID-19 Procedures

Baseline

To safely adhere to COVID-19 procedures recruitment and baseline visits may be conducted remotely via telephone. Eligible participants will receive the consent form via DocuSign (or mail, if preferred and enough time is available) prior to meeting with research staff to allow time for review. Research staff will then conduct an informed consent process to ensure understanding from all participants. If consent was mailed, research staff must wait until signed consent is mailed back before continuing.

Once informed consent is complete, research staff will then assess participants and deliver the intervention, respectively. Participants in the ORP arm will also receive an e-mail with the recovery handout.

Follow-Up Visits

In addition to the baseline visit, all follow up visits may be conducted remotely via telephone by the research assistant (RA) or other staff member who is blinded to the participant's group placement.

Incentives

Participants will receive a $50 Amazon gift card for the Baseline visit, 4-week follow-up visit, and 12-week follow-up visit. Participants will receive a total of $150 for completing all study visits.

Gift cards are ordered through the university's Amazon account where a template is to be downloaded from the site, filled out, and uploaded back onto the site to initiate the ordering process.

Adverse Events

An independent Data Safety Monitoring Board has not been established due to the very low probability of related serious adverse events. Dr. Bill Mihalko will monitor AEs (adverse events) for this study.

If patients experience an adverse event during the study, we will conduct an assessment, complete an Adverse Event form, and follow the adverse event reporting system as required by our IRB and NIH regulations.

Adverse events (AEs) are defined as any unfavorable medical occurrence in a human subject, including any abnormal sign, symptom, or disease temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Serious adverse events (SAEs) are any adverse event temporally associated with the subject's participation in research that meets any of the following criteria:

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred)
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability/incapacity
- Results in a congenital anomaly
- Any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition

All SAEs that are potentially related to the study are to be reported to the Project Coordinator (Ashley Cooper) within one working day. The Project Coordinator will review and escalate to the PI and Study Physician (Drs. Karen Derefinko and Bill Mihalko) via email within 48 hours of initial documentation.

UTHSC's IRB operating procedures regarding AE's can be found here:
https://www.uthsc.edu/research/compliance/irb/researchers/documents/adverse-event-reporting.pdf

MEASURES

SCHEDULING SCRIPTS

Description of Data Collected	Measure/Document Name	Time to Complete	Baseline (pre-op)	4-week	12-week
General					
Eligibility Criteria	Eligibility TKR	1	X		
Contact Information	Contact Info TKR	2	X		
Demographics	Demographics	1	X		
Adverse Events	Adverse Event Reporting Tool	2		X	X
Pain and Opioid Use					
History of Opioid Medication Use	History of Opioid Use	<1	X		
Pain catastrophizing	PCS	2	X		
Opioid Medication Pill Count	Follow-Up Questionnaire	1		X	X
Opioid tolerance and craving	Follow-Up Questionnaire	<1		X	X
Current Opioid Misuse Measure	Current Opioid Misuse Measure	3		X	X
Quality and intensity of pain	SF-MPQ-2	4	X	X	X
Short and long-term patient-relevant outcomes	KOOS JR	1	X	X	X
Use of Non-Narcotic Pain Medication	Non-Narcotic Pain Medication	1	X	X	X
Engagement in Behavioral Pain Management Activities	Behavioral Pain Management Activities	1		X	X
Pre/post knowledge of intervention content	Knowledge Test	1	X	X	
Feedback and Satisfaction	Feedback	2			X
Data Abstraction					
Prescriptions, surgery notes	Data Abstraction Tool	n/a		X	X
			14	16	17

Scheduling Script for BV

What days/times are you usually available? We're usually available Monday-Friday from 8am-4:30pm. *(Find a time before their surgery that works for both of you*.**) Great! I'll get you on the calendar for your first visit on DAY at TIME.** *(Let them know if you or someone else will be the one calling them.)* **You will need to**

have access to your email/computer or smart phone for this visit so you can sign our electronic consent form. Do you have any questions or concerns about this visit? *(Answer any questions they may have.)* **Thanks again for your interest in the TKR Study. We look forward to speaking with you again soon. Have a great day!**

Recruitment Script for BSTR/FU (phone):

We've reached the end of your visit today, all I need to do now is get you scheduled for your next visit. *(Look at participant's next visit window and try to find a day/time that works for them).* **Does DAY/TIME work? Great! I'll place you on the calendar for [VISIT TYPE] on DAY at TIME.** *(If you will not be the one doing the visit, let the participant know! For example: "My colleague, [NAME], will be the one calling you for this visit. Their number is [#].")* **Do you have any questions or concerns about your next visit?**

Recruitment Script for BSTR/FU (in-person):

We've reached the end of your visit today, all I need to do now is get you scheduled for your next visit. *(Look at participant's next visit window and try to find a PT visit that falls in that range).* **Does DAY/TIME work? Great! I'll place you on the calendar for [VISIT TYPE] on DAY at TIME.** *(If you will not be the one doing the visit, let the participant know! For example: "My colleague, [NAME], will be the one doing the visit with you.")* **Do you have any questions or concerns about your next visit?**

STUDY DOCUMENTATION

OneDrive & Filemaker

OneDrive

All study forms (e.g. the consent form, study measures, the regulatory binder, this MOP, the randomization list, etc.) are kept on OneDrive. In order to access the TKR OneDrive folder, permission will need to be granted (i.e. the folder will need to be shared to each person's UT email).

Study Documentation (regulatory binder)

The regulatory binder is kept on OneDrive. This binder keeps track of our recruitment call log, enrollment, gift card payments, and appointment tracking.

TKR Database

The database is located on filemaker, a file hosting application on your UT computer/laptop. In order to access the database, the Research Manager has to request users to be added.

Once added to the TKR database, you will need to open filemaker and navigate to “File” at the top of your screen. Under “File” find “Hosts” and select “Show Hosts.” It should pop up a new screen. On the new screen, hit the plus in the left hand corner (beside the search hosts bar) and type in: “filemaker.uthsc.edu” This should pull up several databases. (I suggest favoriting this host so you can easily access it in the future). You can either scroll or search for TKR to find the specific database: “CTSI TKR.” (You can also add this specific database to your favorites.)

Now open the database by double clicking on the icon. You will log in with your UT net ID and password.